

## Intramedullary versus extramedullary internal fixation for unstable intertrochanteric fracture, a meta-analysis

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### ABSTRACT

**Objective:** The aim of this meta-analysis was to explore the difference between and compare intramedullary fixation (IF) and extramedullary fixation (EF) for unstable intertrochanteric fractures.

**Methods:** We searched Pubmed database and Cochrane library following by including and excluding articles based from inception to December, 2016. All randomized controlled trials (RCTs) comparing IF and EF for unstable intertrochanteric fractures were assessed and selected by two researchers independently. Data were analyzed using Review Manager 5.1 version.

**Results:** 17 RCTs were enrolled in our meta-analysis comparing IF and EF and showed evidence that IF had lower rate of implant failure RR = 0.2695%CI 0.13–0.51, P < 0.0001 and re-operation (RR = 0.60, 95% CI 0.37–0.98, P = 0.04), while there was no statistical differences of cut-out, postoperative infections and other complications. Moreover, PPM scores verified that IF had better postoperative hip mobility recovery (MD = 0.87, 95%CI 0.08–1.66, P = 0.03).

**Conclusion:** IF has lower incidence of failure of implant and reoperation and shows better postoperative functional recovery when treating adult unstable intertrochanteric fracture while the most postoperative complications were not statistically different from EF.

**Level of evidence:** Level I, therapeutic study.

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### Introduction

Intertrochanteric fractures are one of the elementary orthopedic clinical problems, that are commonly resulted from low energy injuries and lead to severe functional defects and heavy socioeconomic pressure.<sup>1</sup> The incidence of intertrochanteric fracture has been kept increasing recently and the mortality rate maintains 30% within 5 years after fracture.<sup>2</sup> The internal fixations are usually considered as prior options for treatments that can enable the patient to have postoperative early mobilization, good functional recovery and less complications.<sup>3,4</sup> With the time of invention and promotion internal fixation devices, the diversity of devices brings orthopedic surgeons more choices, such as intramedullary fixation (IF) (e.g. gamma nail, PFNA) or extramedullary fixation (EF) (e.g. SHS, CHS).<sup>5–7</sup>

Since intertrochanteric is an essential area connecting the femoral head and the shaft, the stability of this area is the key goal that orthopedic surgeons should achieve. Recently, the classification of intertrochanteric fracture is based on the stability of this area. Stable intertrochanteric fractures are commonly simple fractures which are less affected by vertical stress during one-leg standing while unstable intertrochanteric fracture always have affected posteromedial or lateral femoral cortex that decreased the resistibility to stress.<sup>8,9</sup>

However, even with increasing number of clinical trials comparing IF with EF for treating unstable intertrochanteric fracture, the reported results still have not reached the consistency.<sup>10–12</sup> Although there were several systematic reviews and meta-analysis comparing the differences between two kinds internal fixation devices, the findings are still in need of more evidence.<sup>13–15</sup> In the same time, novel devices and surgeon's experience with device also updates with time. Thus, in this study, we conducted a meta-analysis to achieve a detailed comparison and evaluation of IF and EF for unstable intertrochanteric fractures.

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## Materials and methods

### Interventions

IF represents an internal fixation with an intramedullary nail inserting into the femoral bone marrow cavity, for instance intramedullary hip screw (IMHS), gamma nail (GN), proximal femoral nail (PFN), Targon proximal femoral nail (Targon PFN), proximal femoral nail anti-rotation (PFNA), Holland nail and INTERTAN nail (INT), while EF including Sliding hip screw (SHS), as known as Richard screw or AMBI screw, Dynamic hip screw (DHS), Compression hip screw (CHS), Medoff sliding plate (MSP), Percutaneous compression plating (PCCP), Locking compression plate (LCP) and Less invasive stabilization systems (LISS), stands for internal fixations applied outside the marrow cavity for reduction and stabilization. In this meta-analysis, we categorized IF and EF groups to maintain the information integrity according to Cochrane collaboration.<sup>16</sup>

### Search strategy

The database of PubMed database and Cochrane Central Register of Controlled Trials (CENTRAL) were searched from inception up to Jan, 31, 2017. We developed search strategy with target items as followed, #1 “Trochanteric Fractures”, “Fractures, Trochanteric”, “Intertrochanteric Fracture”, “Fractures, Intertrochanteric”, “Hip Fractures”; #2 “Fracture Fixation, Intramedullary”, “Fixations, Intramedullary Fracture”, “Fracture Fixations, Intramedullary”, “Intramedullary Fracture Fixation”, “Intramedullary Fracture Fixations”, “Osteosynthesis, Fracture, Intramedullary”, “Intramedullary Nailing”, “Intramedullary Nailings”, “Nailings, Intramedullary”, “Nailing, Intramedullary”, #3 “Fixation, Internal Fracture”, “Fixations, Internal Fracture”, “Fracture Fixations, Internal”, “Internal Fracture Fixation”, “Internal Fracture Fixations”, “Osteosynthesis, Fracture”, “Fracture Osteosyntheses”, “Fracture Osteosynthesis”, “Osteosyntheses, Fracture”, #3 “Fracture Fixation, Internal”, “Fixation, Internal Fracture”, “Fixations, Internal Fracture”, “Fracture Fixations, Internal”, “Internal Fracture Fixation”, “Internal Fracture Fixations”, “Osteosynthesis, Fracture”, “Fracture Osteosyntheses”, “Fracture Osteosynthesis”, “Osteosyntheses, Fracture”; #4 “randomized controlled trial”, “randomized [Title/Abstract] OR placebo [Title/Abstract]”.

### Inclusion and exclusion criteria

Prospective randomized controlled clinical trials (RCTs) comparing IF and EF for treating unstable intertrochanteric fractures in adults were considered being enrolled as shown in Flowchart (Fig. 1). Unstable intertrochanteric fractures were categorized according to AO/OTA classification (AO/OTA 31 A2.2–A3) and Evans-Jensen classification (II–V type). RCTs published in English with related titles and abstracts were screened by two independent reviewers.

### Outcomes of interest

The potential outcomes of interest included intraoperative and postoperative indexes. Intraoperative indexes were Cleveland zone and tip-apex distance (TAD) while postoperative indexes included adverse events, such as cut-out, fracture of femoral shaft, reoperation, failure of the implant, other complications and hip functional evaluation scores, Harris hip score (HHS) and Parker Palmer hip mobility (PPM).<sup>17,18</sup>

### Risk of bias assessment and data extraction

Two independent reviewers screened the abstracts and full-text of eligible studies to evaluate the risk of bias of included researches using a tool recommended by Cochrane collaboration.<sup>19</sup> For evaluating the surgeon's experience on using devices, a “high” would be marked if there was not enough information whether the research avoided learning curve problem.

### Statistical analysis

Review Manager 5.3 software was employed to process statistical analysis. Continuous data was calculated with weighted mean difference (MD) while dichotomous data calculated with relative risk (RR). Both results adopted a corresponding 95% confidence interval (CI). A P value of <50% was considered significant. The heterogeneity was evaluated between comparisons though I-square ( $I^2$ ) test and Chi-square ( $\chi^2$ ) test. A fixed effect model was applied when  $I^2 < 50\%$  otherwise a random effect model was enabled.

## Results

### Characteristics of the studies

17 RCTs were recruited based on the search strategy and inclusion and exclusion criteria. In total, 2653 cases with average age ranging from 53.95 to 84.6 were enrolled, of which the sample number ranged from 12 to 203 cases. Table 1.

### Position of implant and tip-apex distance (TAD)

The Cleveland zone and TAD of IF and EF group was evaluated on postoperative radiographs according to the introduction and description of Parker and Baumgartner.<sup>20,21</sup> The ideal cephalic implant position as known as Cleveland zone was confirmed to be “center-center” position. There were 5 RCTs provided proper data of Cleveland zone of both internal fixation devices as shown in Fig. 2.<sup>22–25</sup> It showed that there was no difference of number of Cleveland zone between IF and EF group (RR = 0.96, 95%CI 0.87–1.05, P = 0.36) and no evidence of heterogeneity ( $\chi^2 = 1.20$ , df = 3, P = 0.75,  $I^2 = 0\%$ ). As shown in Fig. 3, 3 RCTs measured and the TAD for both groups. It showed that TAD value is significant higher in IF group than that in EF group (MD = 0.85 95%CI 0.08–1.62, P = 0.03) and no evidence for heterogeneity ( $\chi^2 = 1.45$ , df = 2, P = 0.48,  $I^2 = 0\%$ ).

### Cut-out

10 RCTs concerned about the most important complication, cut-out.<sup>22–31</sup> Totally, 1409 patients were involved in this meta-analysis, the result showed that the incidence of cut out had no significant difference between two kinds devices without evidence of heterogeneity (RR = 0.67, 95%CI 0.40–1.12, P = 0.12,  $\chi^2 = 9.87$ , df = 9, P = 0.36,  $I^2 = 9\%$ ) (shown in Fig. 4).

### Failure of implant

8 RCTs pointed out the failure of implant which would lead to severe consequences to the stability and function of the affected limb as shown in Fig. 5.<sup>23,24,26,29–33</sup> The IF group had significantly less failure of implant than EF group (RR = 0.26, 95%CI 0.13–0.51, P < 0.0001). No evidence of significant heterogeneity was found ( $\chi^2 = 6.74$ , df = 7, P = 0.46,  $I^2 = 0\%$ ).

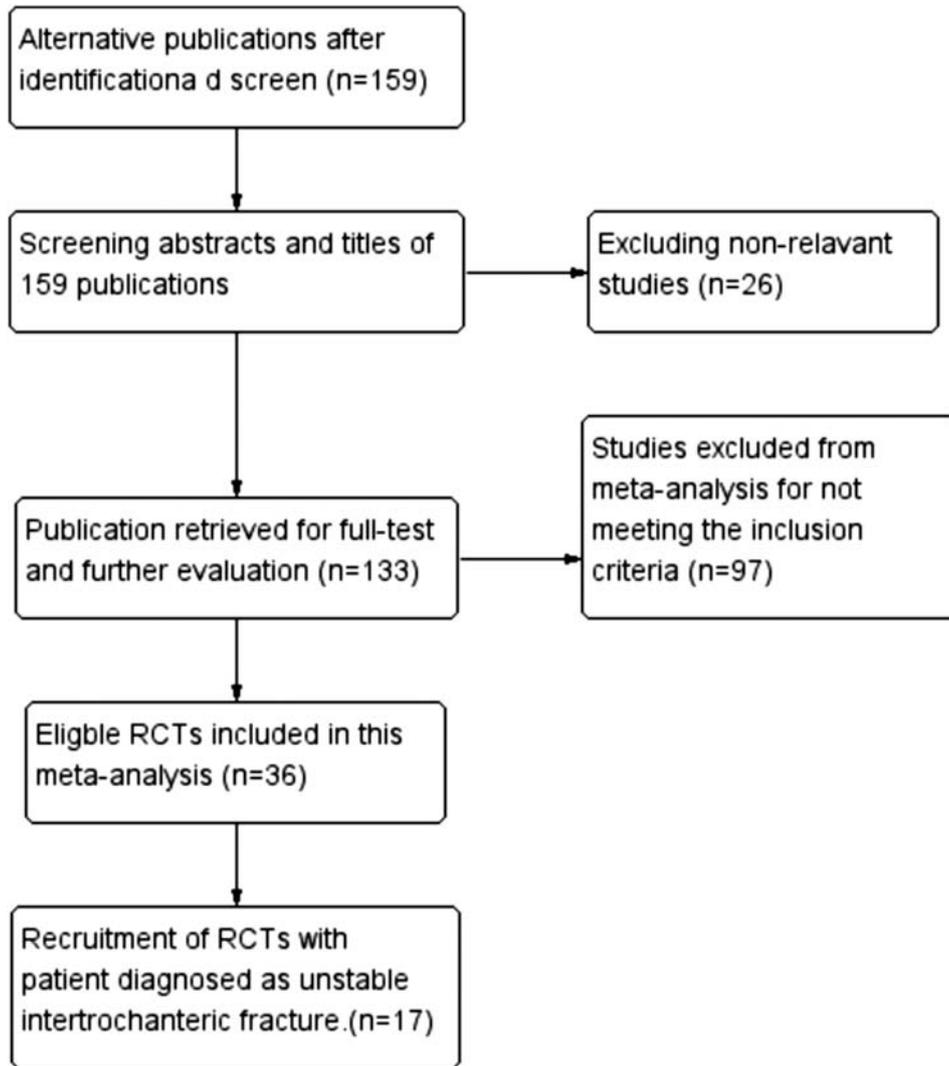


Fig. 1. Flowchart of methodological search strategy and inclusion and exclusion criteria.

**Table 1**  
Characteristics of included studies.

		Interven		Sample size		m/f		Age		Stable		Unstable		Follow-up
Author	year	IF	EF	IF	EF	IF	EF	IF	EF	IF	EF	IF	EF	/month
Aktselis	2014	GN	ABMI	40	40	12/28	12/28	82. ± 5.8	83.1 ± 6.5	NA	NA	40	40	12
Barton	2010	LGN	SHS	100	110	19/81	25/85	83.1 (42–99)	83.3 (56–97)	NA	NA	100	110	12
Baumgaertn	1998	IMHS	CHS	67	68	NA	NA	NA	NA	31	36	35	33	24
Ekström	2007	PFN	MSP	105	98	25/80	25/73	82 (48–96)	82 (52–97)	NA	NA	82	87	12
garg	2011	PFNA	DHS	42	39	32/10	12/27	60.2 (60–80)	64.3 (60–78)	NA	NA	42	39	12
Haq	2014	PFN	DFLCP	20	20	10/10	18/2	55.55 ± 17.09	53.95 ± 14.75	NA	NA	20	20	12
Harrington	2002	IMHS	CHS	50	52	10/40	11/41	83.8 ± 8.5	82.1 ± 8.6	NA	NA	50	50	12
Leung	1992	GN	DHS	93	93	26/68	30/63	80.86 ± 8.41	78.27 ± 9.46	30	20	63	73	6.8–7.5
Miedel	2005	GN	MSP	109	108	NA	NA	84.6 ± 0.6	82.7 ± 0.6	NA	NA	93	96	12
Papasimos	2005	PFN	AMBI	40	40	17/23	14/26	79.4	81.4	NA	NA	40	40	12
Reindl	2015	GN/INT/TN	DHS	112	92	57/55	31/61	NA	NA	NA	NA	112	92	12
Sadowski	2002	PFN	DCS	203	197	7/13	5/14	80 ± 13	77 ± 14	NA	NA	20	19	12
Tao	2013	PFNA	LISS	21	21	5/16	11/10	82.5 ± 7.9	80.7 ± 8.1	NA	NA	21	21	13
Tao	2013	PFNA	LISS	14	12	5/9	4/8	77.4 ± 6.3	77.2	NA	NA	14	12	13
Utrilla	2005	GN	CHS	104	106	NA	NA	NA	NA	NA	NA	23	31	13.6 (12–30)
verettas	2010	GN	DHS	59	59	20/40	15/54	79.22 ± 7.99	81.03 ± 6.38	NA	NA	59	59	10days
Zehir	2014	PFNA	DHS	96	102	37/59	39/63	77.22 ± 6.82	76.86 ± 6.74	NA	NA	96	102	6
Zou	2009	PFNA	DHS	58	63	12/46	15/47	65 (37–91)	65 (34–89)	42	52	16	11	12

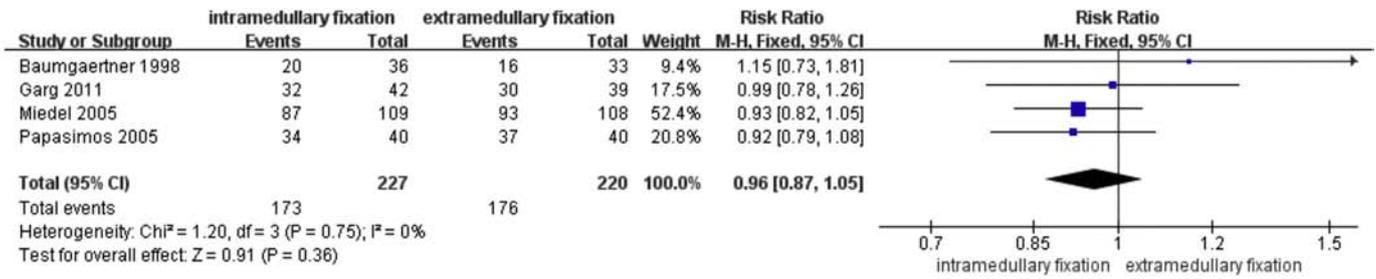


Fig. 2. The comparison of position of implant between IF and EF groups.

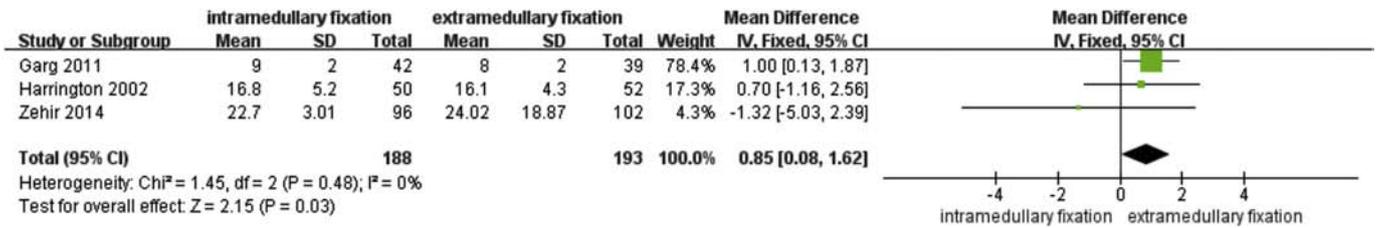


Fig. 3. The comparison of TAD between IF and EF groups.

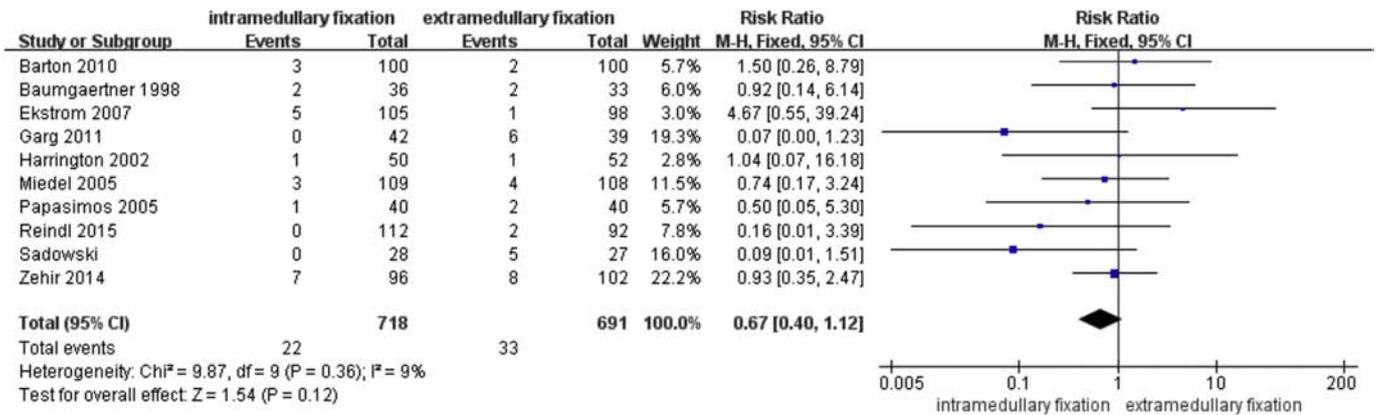


Fig. 4. The comparison of cut-out between IF and EF groups.

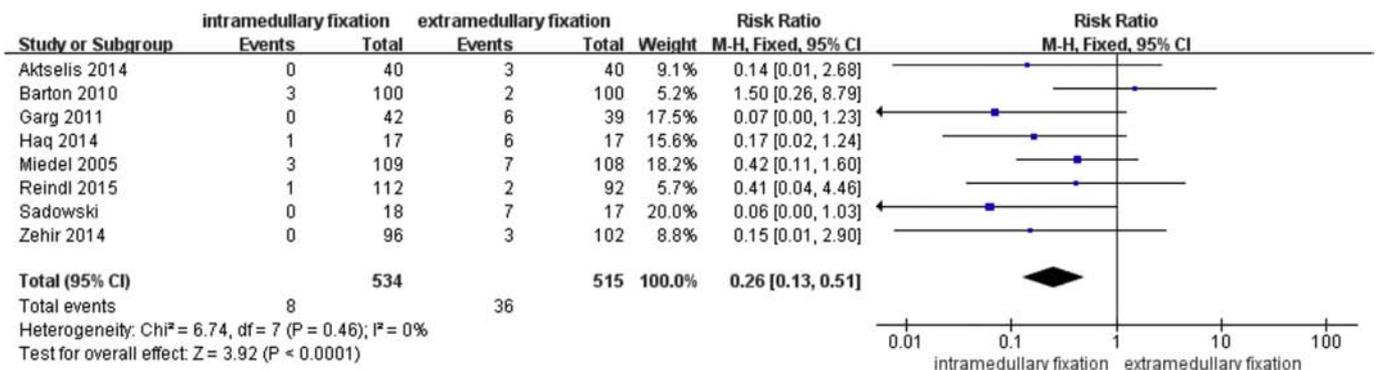


Fig. 5. The comparison of failure of implant between IF and EF groups.

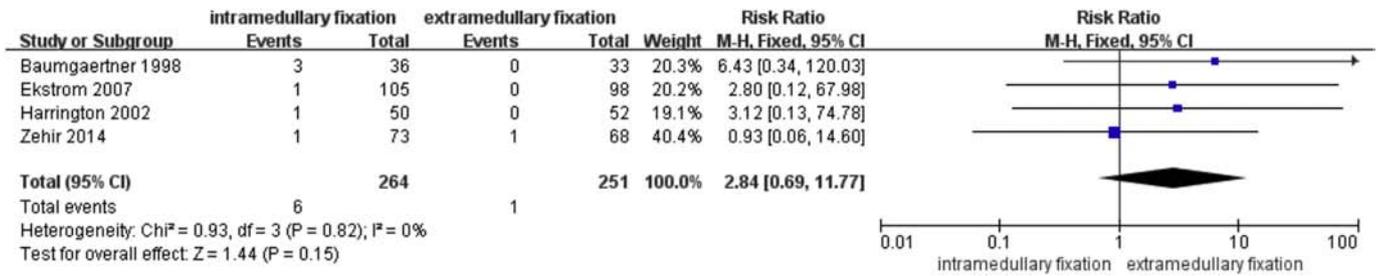


Fig. 6. The comparison of fracture of femoral shaft between IF and EF groups.

Fracture of the femoral shaft

There were 12 RCTs providing data of postoperative fracture of femoral shaft with 2936 patients included.<sup>22,27,28,31,34–41</sup> As shown in Fig. 6, even though there were more cases of fracture of femoral shaft reported, this difference was not statistically different between IF and EF groups (RR = 2.84, 95%CI 0.69–11.77, P = 0.15). No evidence of heterogeneity was found in this comparison (Chi<sup>2</sup> = 0.03, df = 3, P = 0.82, I<sup>2</sup> = 0%).

Reoperation

10 RCTs reported the adverse event numbers of reoperation as shown in Fig. 7.<sup>22–26,29–31,33,42</sup> 1351 cases were involved and our results indicated that IF group had significantly lower incidence of reoperation than EF group (RR = 0.60, 95%CI 0.37–0.98, P = 0.04) and no significant heterogeneity was found between groups (Chi<sup>2</sup> = 12.89, df = 9, P = 0.17, I<sup>2</sup> = 30%).

Postoperative infection

We pooled data of infections including superficial infection, deep infection and general infection for this meta-analysis. In total, 11 RCTs were involved in this analysis.<sup>24,25,27,30,31,33,38,42–45</sup> After analyzing, we found that the incidences of superficial infection (RR = 0.77, 95%CI 0.46–1.30, P = 0.33) and general infection (RR = 0.87, 95%CI 0.46–1.64, P = 0.66) between two groups had no statistically significant while IF group had less deep infection (RR = 0.20, 95%CI 0.04–0.92, P = 0.04). Within all comparisons, no heterogeneity was found (shown in Fig. 8).

Other complications

We pooled data for other adverse events, for instance postoperative DVT, fracture non-union and hip pain complain, and compared between IF and EF groups. In Fig. 9, it showed that regarding to other adverse events recorded in both groups, no significant difference was found among postoperative DVT (RR = 1.01, 95%CI 0.47–2.20, P = 0.97), fracture non-union (RR = 0.40, 95%CI 0.12–1.38, P = 0.15) and hip pain (RR = 1.06, 95%CI 0.50–2.26, P = 0.88), and No heterogeneity was indicated among these comparisons.

Hip functional evaluation

There were 3 RCTs demonstrating their evaluation and assessment of postoperative hip function.<sup>33,43,44</sup> They measured the HHS and PPM score system. However, after analyzing the data respectively, we found no statistical difference though HHS (MD = 4.41, 95%CI –3.81–12.62, P = 0.29), but a significant difference though PPM score (MD = 0.87, 95%CI 0.08–1.66, P = 0.03), revealing that patient received IF devices could have better hip function scores than who received EF devices. A high heterogeneity was found in HHS comparison meanwhile no heterogeneity was detected in PPM analysis (Figs. 10 and 11).

Discussion

The proper and ideal treatment for unstable intertrochanteric fractures are still remaining the top problems for orthopedic surgeons all over the world.<sup>46,47</sup> Researches have illustrated that due to

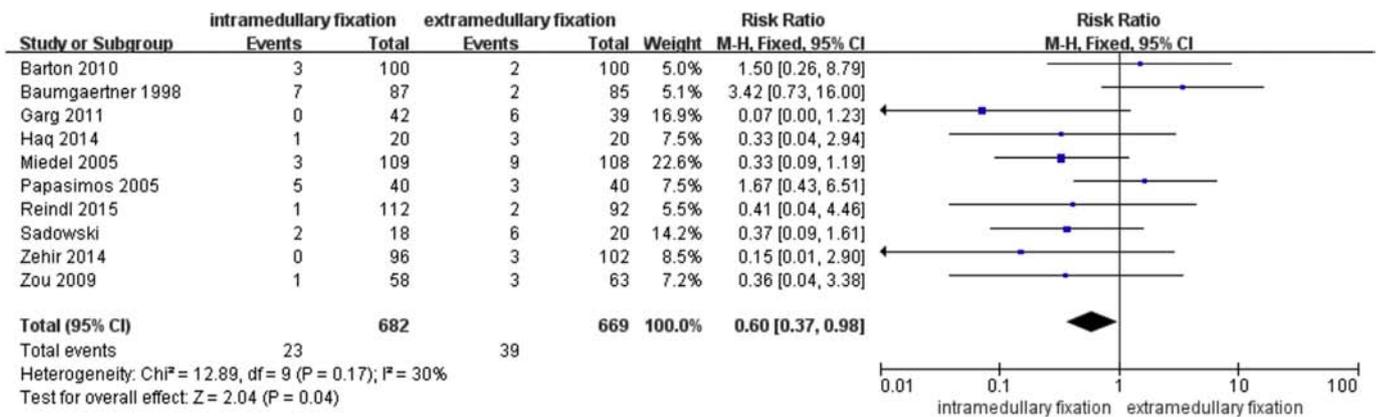


Fig. 7. The comparison of reoperation rate between IF and EF groups.

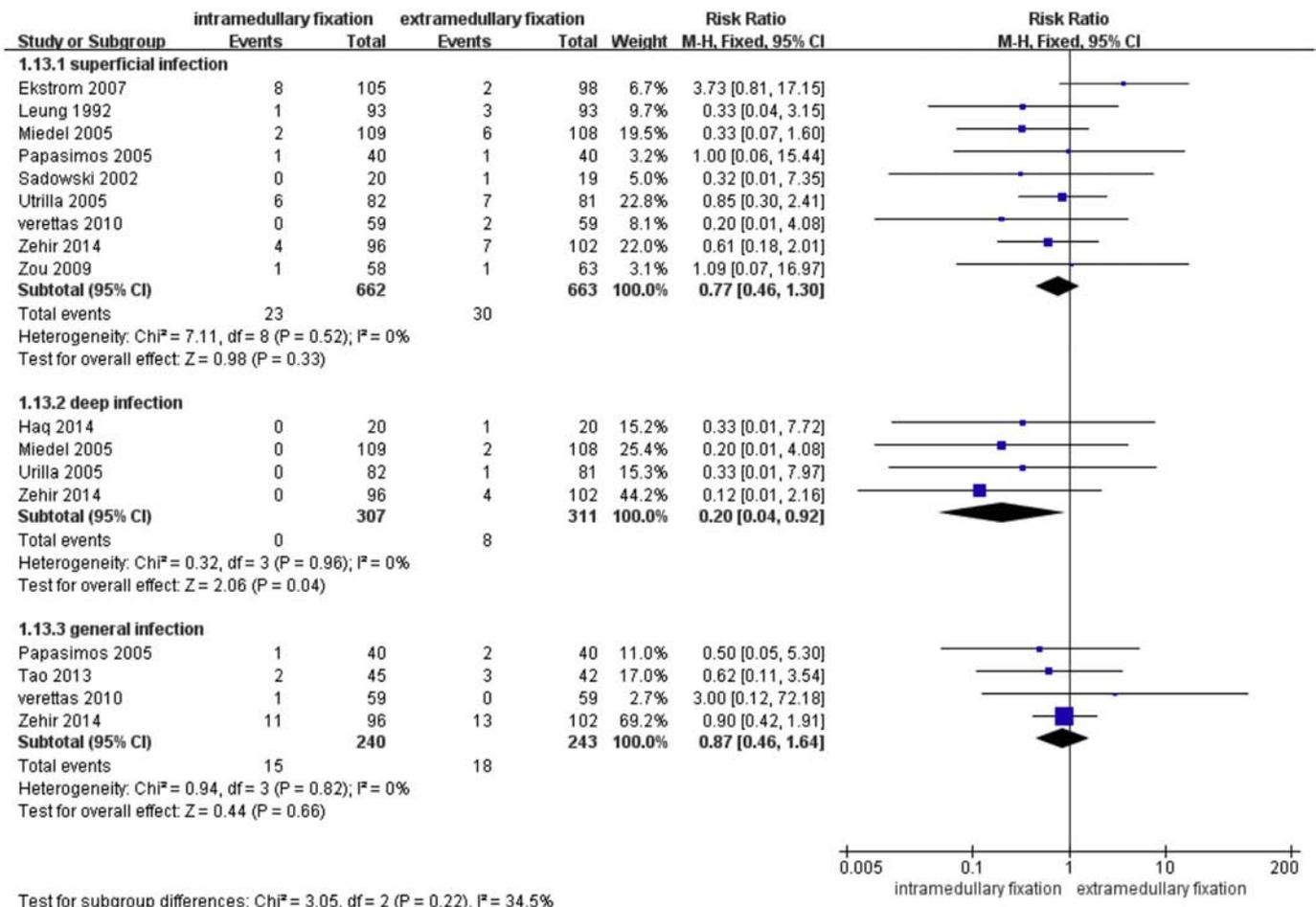


Fig. 8. The comparisons of superficial infection, deep infection and general infection between IF and EF groups.

the fractures of proximal femoral medial cortex wall, the stress load to implant as well as the risk of implant failure would increase.<sup>8</sup> Furthermore, it was reported that the failure of implant would be increased by using SHS for in AO/OTA 31A3 type intertrochanteric fracture.<sup>48</sup> A recent Cochrane systematic review and meta-analysis conducted by Parker et al pointed out that for stable intertrochanteric fracture, either IF and EF can achieve good reduction and stabilization results. On the other hand, for unstable fracture, they recommended the usage of IF prior to EF with the lack of functional comparison and more solid evidence.<sup>14</sup> Thus, in this meta-analysis, we intended to recruit latest published RCTs concerning about the IF and EF devices treating unstable intertrochanteric fractures. We have developed search strategy and followed the direction of Cochrane collaboration guidelines. After restricted search and screen, 17 eligible RCTs were included with totally 2653 cases. Among them, Baumgaertner, Leung and Zou studied both stable and unstable intertrochanteric fracture with separated results.<sup>22,38,42</sup>

Since the internal fixation becomes one of the mainstream surgical treatments for intertrochanteric fracture, clinical trials for testing and applying different internal fixation devices with different constructions have been continued all the time. With updating and renovating of internal fixations, intra- and extramedullary fixations could be categorized based on their implant design. However, the cut-out of the cephalic implant after surgery has remained a main complication for both IF and EF devices.<sup>49,50</sup> Our meta-analysis found no statistical significant difference of

cut-out between IF and EF groups, which was consistency with previous studies.<sup>14,15</sup> Besides cut-out, bone non-union, infection and other complications were taken into this research as well. Previous evidence-based study indicated that IF device GN might lead to more complications than EF device SHS, but our latest data uncovered that although IF devices held lower rate of deep infection, other complications including fracture non-union, DVT, superficial and general infections and postoperative hip pain did not demonstrated significant difference.<sup>15</sup>

TAD and Cleveland zone are considered as important factors related to cephalic implant cut-out.<sup>51–53</sup> TAD was measured according to AP and lateral view radiographs and calculated as the summation of the distance from the tip of the cephalic implant to the apex of the femoral head on both views.<sup>20</sup> Studies proposed the maximal safe distance was 25 mm. TAD > 25 mm would be regarded with high risk of cut-out. In this meta-analysis, comparisons on TAD showed that IF group had higher mean TAD value. However, the average TADs of IF and EF groups were neither > 25 mm, we can't directly connect the TAD to cut-out risk. In the meantime, Cleveland zone comparison showed that IF and EF groups had similar implant placement. Comprehensively, both TAD and Cleveland zone showed similar outcome of cut-out. The cut-out between IF and EF groups had no significant difference.

What is also noteworthy in this meta-analysis, our results testified that IF had less adverse events, such as failure of implant, reoperation and deep infection. Failure of implant represented mechanical failures, such as cut-out, implant breakage, non-union,

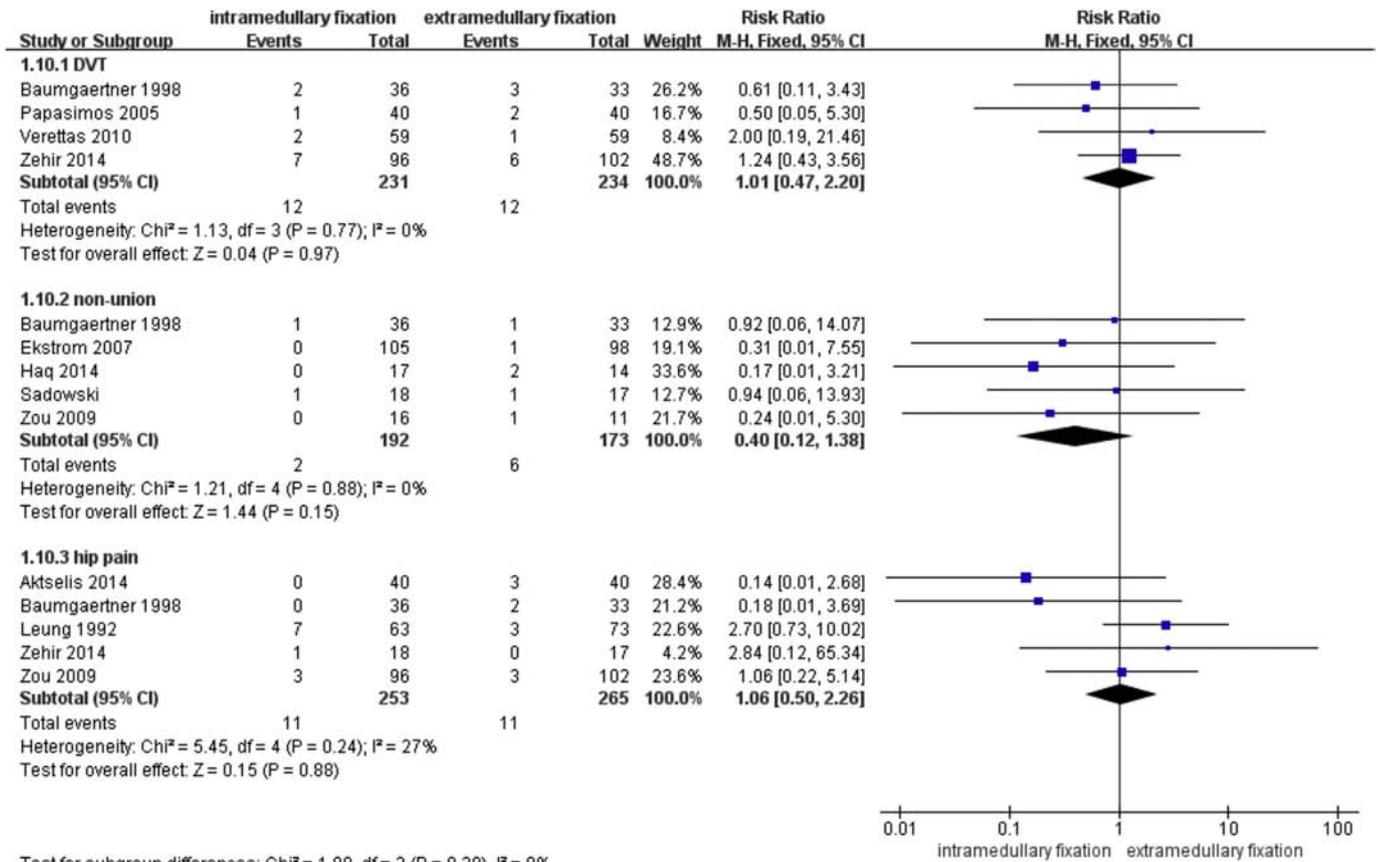


Fig. 9. The comparisons of other complications between IF and EF groups.

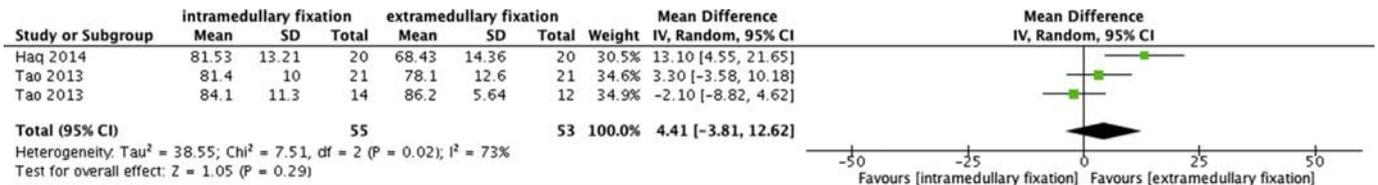


Fig. 10. The comparison of HHS between IF and EF groups.

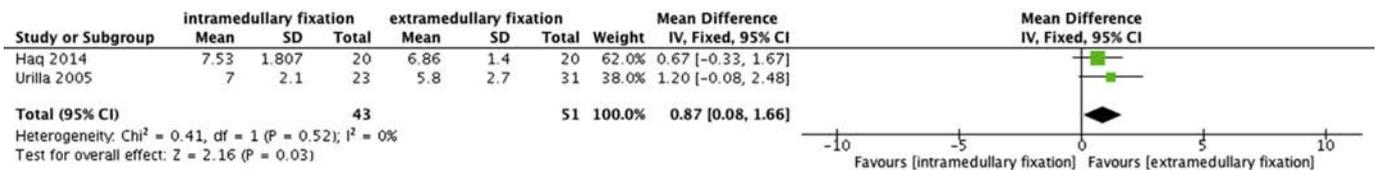


Fig. 11. The comparison of PPM between IF and EF groups.

surgical related secondary fracture of the femoral shaft. Our analysis clearly showed that IF had lower incidence of failure of implant. The possible explanation would be IF device's loading sharing design, the occurrence of intraoperative fracture of the lateral trochanteric wall leading to extra stress on the distal femoral fragment and the difficulty of reduction.<sup>29,31</sup>

The hip function recovery was evaluated by two hip function and mobility score systems, HHS and PPM. Respectively, each comparison contains two RCTs. Although the HHS stated no significant difference, the PPM showed that IF group had better hip mobility after surgery. More RCTs reporting hip functional recovery status are needed for more solid evidence.

During researching and assessing the effect of IF and EF internal fixations, the learning curve problem of surgeons participating in the operations should be paid closed attention, which might affect the evaluation of RCTs.<sup>54</sup> As the IF is relatively new technique, the familiarity of one surgeon with two devices would have great impacts during surgeon's performance and application. It may lead to the unnecessary intraoperative fractures around the insertion area. Utrilla et al specified the learning curve issue about using GN, but for now, there was no suitable RCT and evidence-based study concerning about the learning curve and fixation effect.<sup>44</sup>

In this meta-analysis, we conducted a comprehensive comparison and analysis following the methodological directions from Cochrane collaboration. However, there are still some limitations. Multiple lingual researches should be expanded and screened. More specified comparisons between individual internal fixation device are in need of stronger evidence.

## Conclusion

Above all, the lower rate of failure of implant, reoperation and deep infection, the similar other adverse event and better post-operative hip mobility recovery demonstrated the priority of using IF when treating unstable intertrochanteric fractures.

## Conflicts of interest

All authors declare that there is no conflict of interest in this study.

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